UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

In re LANTUS DIRECT PURCHASER ANTITRUST LITIGATION	CIVIL ACTION NO. 16-12652-JGD

MEMORANDUM OF DECISION AND ORDER ON DEFENDANT'S MOTION TO DISMISS SECOND AMENDED COMPLAINT

October 24, 2018

DEIN, U.S.M.J.

I. INTRODUCTION

By Memorandum of Decision and Order (Docket No. 40) dated January 10, 2018, this court dismissed the plaintiffs' Amended Complaint without prejudice. Thereafter, plaintiffs were granted leave to and did file a Second Amended Complaint (Docket Nos. 49, 51). Defendant has now moved to dismiss the Second Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) (Docket No. 54) (the "Motion to Dismiss"). Plaintiffs have opposed the Motion to Dismiss (Docket No. 59) ("Opp.") and defendant has filed a Reply (Docket No. 62). After oral argument on the Motion to Dismiss, the parties submitted supplemental letters to the court (Docket Nos. 71, 72) addressing questions raised at oral argument. The court has carefully considered the parties' submissions and arguments made in open court. For the reasons detailed herein, the Second Amended Complaint fails to state a claim on which relief can be granted. The Motion to Dismiss is therefore ALLOWED and the Second Amended Complaint is dismissed with prejudice.

II. STATEMENT OF FACTS[1]

Since the Second Amended Complaint is premised on and merely expands upon the allegations of the First Amended Complaint, this court will assume the reader's familiarity with its earlier decision and will not repeat the extensive factual history laid out therein. All of those facts remain relevant to the instant analysis. What follows is a brief overview of the facts and regulatory context for this Motion.

The defendant, Sanofi-Aventis US LLC ("Sanofi"), is a life sciences company that sells, among other medicines, Lantus — an insulin glargine solution used for management of diabetes. See SAC ¶ 3. Lantus is sold in vial form or, as particularly relevant here, in an injector pen known as Lantus SoloSTAR. Id. Plaintiffs, FWK Holdings, LLC and Cesar Castillo, Inc., are purchasers of Lantus and allege that Sanofi unlawfully extended its period of market exclusivity over insulin glargine products and charged supra-competitive prices for Lantus after February 2015. Id. ¶¶ 14, 15, 196, 197. On behalf of themselves and a purported class of similar purchasers, the plaintiffs seek damages for having had to pay those supra-competitive prices. The plaintiffs define the class as anyone who "purchased Lantus (in cartridges or SoloSTAR) directly from Sanofi at any time between February 13, 2015 and December 31, 2016 or until the anticompetitive effects of Sanofi's conduct cease[.]" Id. ¶ 486.

The plaintiffs assert two counts in their Complaint, monopolization and attempted monopolization. Both counts are antitrust claims arising under § 2 of the Sherman Act (15 U.S.C. § 2). Both counts are premised on the plaintiffs' arguments that Sanofi engaged in an

[1] Unless otherwise noted, the facts are derived from the Second Amended Complaint (Docket No. 51) ("SAC").

exclusionary conduct scheme consisting of improperly listing patents in the U.S. Food & Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), commencing and maintaining a sham litigation lawsuit against Eli Lilly & Company ("Lilly"), and engaging in a pattern of anticompetitive serial petitioning. Id. ¶¶ 496-514.

As relevant for this opinion, Sanofi is the holder of "formulation" patents covering preparations of insulin, and "pen" patents covering injector pens or components thereof. Id. ¶¶ 216-217, 249-254, 354, 390-402. As with Sanofi's previous motion to dismiss (Docket No. 21), the instant Motion focuses largely on Sanofi's conduct related to U.S Patent No. 8,556,864 ("the '864 Patent"), titled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." SAC Ex. I. This patent covers a part used in Sanofi's insulin injector pen, the Lantus SoloSTAR. The plaintiffs allege that Sanofi improperly listed the '864 Patent in the Orange Book and commenced sham litigation against Lilly asserting infringement of that patent. Sanofi denies that its conduct related to the '864 Patent was anticompetitive, and argues that because the '864 Patent stood as a lawful bar to competition, the plaintiffs' other allegations fail due to issues of causation.

The Orange Book is intended to put other drug manufacturers on notice of relevant patents. Companies seeking FDA approval of a new drug submit a new drug application ("NDA") pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). Those companies must list any patents in the Orange Book "which claim[] the drug for which the applicant submitted the application or which claim[] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C.

§ 355(b)(1). Sanofi submitted an NDA for Lantus and a Supplemental NDA for Lantus SoloSTAR, and has listed patents for each. See SAC ¶¶ 182, 203, 280, 282. The plaintiffs claim that Sanofi improperly listed certain patents, including the '864 Patent, in the Orange Book, thereby illegally gaining the ability to commence litigation against competitors and extend its period of exclusivity, as explained below.

Under the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), known as the Hatch-Waxman Amendments, drug manufacturers seeking approval to sell products similar to already approved brand drugs can file an application for approval which relies on a brand manufacturer's NDA. Id. ¶¶ 35, 37, 71. This makes it easier for follow-on or generic manufacturers to gain FDA approval. In doing so, the new manufacturer must certify as to how their product impacts the patents that the brand drug manufacturer listed for its original NDA.

As relevant here, Lilly submitted an application for its insulin glargine product Basaglar, relying on Sanofi's NDA submissions for its Lantus products. Basaglar, like the Lantus SoloSTAR, provides insulin glargine in an injector pen. See id. ¶¶ 300-02. Lilly planned on using its own pen for the product, the KwikPen, which Lilly had previously been using for other products. Id. Because Lilly relied on Sanofi's submissions, it had to file certifications related to Sanofi's patents for Lantus and Lantus SoloSTAR. With the exception of one patent, Lilly certified that Sanofi's listed patents "were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of [Basaglar]." Id. ¶ 306. This type of certification is known as a "paragraph IV certification." Filing a paragraph IV certification "may provoke litigation. The patent statute treats such filing as an act of technical infringement and provides

the brand company an opportunity to sue." Id. ¶ 79; 35 U.S.C. § 271(e)(2)(A). Thus, if Sanofi had reason to believe that Lilly's product infringed any of its listed patents when Lilly filed its paragraph IV certification, it had the opportunity to sue Lilly prior to the FDA approving Lilly's product. "If the branded drug manufacturer initiates a patent infringement action against its would-be competitor within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the [new drug application] until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the [new] product." Id. ¶ 80; 21 U.S.C. § 355(c)(3)(C).

After receiving Lilly's paragraph IV certifications, Sanofi sued Lilly for patent infringement on two of the formulation patents and two of the pen patents, including the '864 patent. SAC ¶ 325. The plaintiffs claim that this litigation was a sham because it was based on improper Orange Book listings and because Sanofi had no reasonable basis for thinking that its patents were infringed. As is provided for by 21 U.S.C. § 355(c)(3)(C), the lawsuit against Lilly triggered an automatic stay of FDA approval for Basaglar. Id. ¶ 326. On September 28, 2015, the morning of trial, Lilly and Sanofi settled the litigation. Id. ¶ 375. As part of the settlement, Sanofi granted Lilly a royalty-bearing license so that Lilly could manufacture and sell Basaglar, and Lilly agreed to delay its launch of Basaglar until December 15, 2016. Id. ¶¶ 375-77.

In addition to the conduct related to Lilly, the plaintiffs include in their Second Amended Complaint additional facts that they claim add to Sanofi's overall anticompetitive scheme. First, the plaintiffs allege that "[e]ven after Sanofi's litigation with Lilly, [Sanofi] expected other companies would soon seek to create affordable follow-on insulin glargine products. To further frustrate those efforts, Sanofi obtained and then listed in the Orange Book an additional

thirteen patents over its SoloSTAR injector pen." Id. ¶ 389 (emphasis omitted). The plaintiffs allege that "[n]one of the new patents claim insulin or insulin glargine. Each claims one or more aspects of the SoloSTAR packaging. All are improperly listed in the Orange Book and serve to frustrate competition." Id. ¶ 403. Second, the plaintiffs allege that Sanofi commenced lawsuits against would-be competitors Merck and Mylan, exhibiting a "pattern of anticompetitive petitioning for which [Sanofi] is independently liable under federal antitrust law, even if each act of petitioning is not independently objectively baseless." Id. ¶ 500.

This court granted Sanofi's first motion to dismiss on January 10, 2018 (Docket No. 40). Therein, this court held that the plaintiffs failed to state a claim related to antitrust liability stemming from improper Orange Book listings because the alleged facts did not show that it was unreasonable to list the '864 Patent. This court also dismissed the plaintiffs' sham litigation claim, ruling that the plaintiffs failed to plead facts which showed that Sanofi's litigation against Lilly involving the '864 Patent was objectively baseless. As the '864 Patent stood as a legal barrier to Basaglar's market entry prior to December 15, 2016, this court dismissed the plaintiffs' remaining allegations for lack of causation. The court's dismissal was without prejudice. The plaintiffs have now submitted a Second Amended Complaint and Sanofi has again moved for this court to dismiss both counts.

Additional facts are included herein as necessary.

III. LEGAL STANDARD

A. Motion to Dismiss for Failure to State a Claim

While Sanofi has moved to dismiss the Second Amended Complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), it argues further that this court

should decline to reconsider its earlier rulings, and, instead, invoke the "law of the case" doctrine. See Mem. in Supp. of Motion to Dismiss (Docket No. 55) at 13-14. The law of the case doctrine holds that "unless corrected by an appellate tribunal, a legal decision made at one stage of a civil or criminal case constitutes the law of the case throughout the pendency of the litigation." Ellis v. United States, 313 F.3d 636, 646 (1st Cir. 2002) (internal citation and quotation omitted). In light of the substantial new allegations of the Second Amended Complaint, however, as well as the extensive arguments presented by the parties, this court has considered the sufficiency of the Second Amended Complaint anew, and applied the 12(b)(6) standard of review. Nevertheless, as detailed below, this court has not altered its decision and incorporates herein the analysis included in its decision of January 10, 2018 (Docket No. 40) (hereinafter, "Order").

Standard of Review

Motions to dismiss under Rule 12(b)(6) test the sufficiency of the pleadings. When confronted with such a motion, the court accepts as true all well-pleaded facts and draws all reasonable inferences in favor of the plaintiff. See Cooperman v. Individual Inc., 171 F.3d 43, 46 (1st Cir. 1999). The court may also consider "implications from documents attached to or fairly incorporated into the complaint . . . facts susceptible to judicial notice . . . [and] concessions in plaintiff's response to the motion to dismiss." Schatz v. Republican State Leadership Comm., 669 F.3d 50, 55-56 (1st Cir. 2012) (internal quotations and citations omitted).

As the First Circuit has explained, in considering the merits of a motion to dismiss, the court proceeds in two steps. First, we "isolate and ignore statements in the complaint that simply offer legal labels and conclusions or merely rehash cause-of-action elements." Id. at 55.

Second, we "take the complaint's well-pled (*i.e.*, non-conclusory, non-speculative) facts as true, drawing all reasonable inferences in the pleader's favor, and see if they plausibly narrate a claim for relief." Id. Dismissal is only appropriate if the complaint, so viewed, fails to allege "a plausible entitlement to relief." Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559, 127 S. Ct. 1955, 1967, 167 L. Ed. 2d 929 (2007)). "Plausible . . . means something more than merely possible[.]" Schatz, 669 F.3d at 55. "The bottom line is that the combined allegations, taken as true, must state a plausible, not merely conceivable, case for relief." Carrero-Ojeda v. Autoridad de Energia Electrica, 755 F.3d 711, 718 (1st Cir. 2014) (internal citations and quotations omitted). "Engaging in this plausibility inquiry is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" Germanowski v. Harris, 854 F.3d 68, 72 (1st Cir. 2017) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 679, 129 S. Ct. 1937, 1950, 173 L. Ed. 2d 868 (2009)).

B. Monopolization and Attempted Monopolization Under the Sherman Act

Plaintiffs bring two counts under the Sherman Act, 15 U.S.C. § 2, one for monopolization and the other for attempted monopolization. SAC ¶¶ 496-514. In order to be successful on a claim under § 2 of the Sherman Act, a plaintiff must "demonstrate (1) that the defendant possesses monopoly power in the relevant market, and (2) that the defendant has acquired or maintained that power by improper means." Town of Concord v. Boston Edison Co., 915 F.2d 17, 21 (1st Cir. 1990) (internal quotations and citations omitted). "[A] practice, a method, a means, is 'improper' if it is 'exclusionary.' To decide whether [a company's] conduct was exclusionary, we should ask whether its dealings with [a competitor] went beyond the needs of ordinary business dealings, beyond the ambit of ordinary business skill, and 'unnecessarily

excluded competition' from the [] market." Barry Wright Corp. v. ITT Grinnell Corp., 724 F.2d 227, 230 (1st Cir. 1983) (internal citations omitted). Thus, successful claims of monopolization must establish "that the defendant 'has engaged in impermissible 'exclusionary' practices with the design or effect of protecting or enhancing its monopoly position.'" Boston Sci. Corp. v. Schneider (Europe) AG, 983 F. Supp. 245, 268 (D. Mass. 1997) (quoting Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 195-96 (1st Cir. 1996)). "In other words, the acquisition and maintenance of the power must be willful, rather than a result of legitimate means such as patents, superior products, business acumen, or historic accident." Id. Finally, "[a]ttempted monopolization under § 2 of the Sherman Act requires proof of (1) anti-competitive or exclusionary conduct; (2) specific intent to monopolize; and (3) a dangerous probability that the attempt will succeed." Id., and cases cited.

Applying these principles compels the conclusion that Sanofi's Motion to Dismiss must be allowed.

IV. ANALYSIS

A. Orange Book Listing

The plaintiffs ask this court to reconsider its prior holding that the Complaint fails to state a claim that Sanofi had unreasonably listed the '864 Patent in the Orange Book. In particular, the plaintiffs continue to assert that the '864 Patent is just for packaging, and that it was improper to list it in the Orange Book since the Patent does not claim the approved drug product. See, e.g., Opp. at 19-24. Sanofi, on the other hand, continues to argue that the '864 Patent was appropriately listed as a "drug delivery system[ ] used and approved in combination with a drug." Reply at 4. This court previously held that "while it may be debatable whether

the Lantus SoloSTAR fits neatly into the category of patents that must be disclosed, it does not fit into the category of patents that must not be disclosed." Order at 21. The allegations in the Second Amended Complaint do not warrant a different conclusion. The court once again concludes that the facts in the Second Amended Complaint are insufficient to show that Sanofi unreasonably or improperly listed the '864 Patent in the Orange Book.

Appropriate Standard of Review

As addressed in this court's prior Order, "Orange Book listing is a statutory obligation and enforcement is a statutory right." In re Lipitor Antitrust Litig., No. 12-2389, 2013 WL 4780496, at *21 (D.N.J. Sept. 5, 2013); see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-02503, 2015 WL 5458570, at *12 (D. Mass. Sept. 16, 2015). Applicants are "required by law" to identify "any patent that 'claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'" In re Buspirone Patent Litig., 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) (quoting 21 U.S.C. § 355(b)(1)).

While companies must list certain patents in the Orange Book, improperly listing a patent may subject the patent holder to antitrust liability. See id. at 373 (conduct in providing information for listing in Orange Book is "not immune from liability under the Sherman Act."). Importantly, however, an improper listing does not give automatic rise to antitrust liability. This court established in its prior Order, and reaffirms here, that in order to establish a claim under the Sherman Act for Orange Book listing, a party must show that the defendant's decision to list a patent was unreasonable. See Order at 19.

The plaintiffs contend that this court was incorrect in using such a reasonableness standard. They argue that the court improperly focused on whether Sanofi reasonably (or unreasonably) believed that the '864 Patent fit within the criteria for patents to be listed in the Orange Book. See Opp. at 24-26. This misconstrues this court's ruling. Sanofi's subjective belief as to the propriety of its interpretation of the listing requirements is not at issue. Rather, as this court previously ruled, and confirms herein, it is objectively reasonable to interpret the Listing Provisions in 21 C.F.R. § 314.53 and the associated FDA Response as allowing the '864 Patent to be listed in the Orange Book as a component of a drug delivery system. Therefore, in listing the '864 Patent, Sanofi did not engage in improper conduct. See Organon, Inc. v. Mylan Pharm., Inc., 293 F. Supp. 2d 453, 460 (D.N.J. 2003) ("given the statutory and regulatory language at the time it submitted the '099 Patent for listing in the Orange Book, Organon had a reasonable basis for the submission, and therefore, Organon's listing was not improper."). While the plaintiffs attempt to distinguish Organon on the grounds that the regulatory language at issue in that case was ambiguous and the Orange Book listing requirements here are not, that attempt must fail. As detailed in this court's prior Order and herein, the listing requirements and associated guidance are subject to differing interpretations. Where there is more than one reasonable interpretation of the listing requirements, and a party follows one of those interpretations, the conduct is not improper.

The '864 Patent is Not Just for Packaging

The plaintiffs argue that the '864 Patent is for packaging and is precluded from being listed in the Orange Book. This court found that argument unpersuasive in its earlier decision. See Order at 20. While the plaintiffs have expanded on their legal arguments in their Second

Amended Complaint, they have not added any substantive facts which compel this court to reach a different result.

As an initial matter, the plaintiffs contend that the Lantus SoloSTAR was approved only as packaging. This contention is belied by the record. Rather, the SoloSTAR was approved as a drug product.

It is undisputed that Lantus SoloSTAR is sold as an injector pen filled with insulin glargine. See SAC ¶ 209. Lantus SoloSTAR was approved as a "disposable insulin injection device." SAC Ex. D. The 2003 Comments and Response from the FDA, discussed in detail in this court's prior Order, indicate that "pre-filled drug delivery systems" are drug products for Orange Book listing purposes. See Order at 7-9 (discussing 68 Fed. Reg. 36676-01, 2003 WL 21391636, at 36,680 (June 18, 2003) ("FDA Response")). As evidenced by the FDA website, of which this court takes judicial notice, insulin injector pens are considered "pre-filled drug delivery systems." FDA, https://www.fda.gov/CombinationProducts/AboutCombination Products/ucm101496.htm#examples (last visited Oct. 22, 2018) (listing as examples of combination products "[p]refilled drug delivery systems (syringes, insulin injector pen, metered dose inhaler)"); see Kader v. Sarepta Therapeutics, Inc., No. 14-14318, 2016 WL 1337256, at *11 (D. Mass. Apr. 5, 2016) (holding that official statements of the FDA made on a government website constitute public records of which the court can take judicial notice). The FDA's SoloSTAR approval letter refers to the Lantus SoloSTAR as a "drug product." SAC Ex. D. ("If you issue a letter communicating important information about this drug product . . . we request that . . . .").

In an effort to avoid this conclusion, the plaintiffs excerpt various phrases from communications between the FDA and Sanofi relating to the proposed labelling for the SoloSTAR in which "the FDA repeatedly referred to the [SoloSTAR] pen as a container" or "packaging." SAC ¶¶ 203-10. The plaintiffs rely on these select comments in concluding that "it was unreasonable for Sanofi to believe that its [supplemental new drug application] approval was for anything other than a package change." Id. ¶ 211. However, these select references must be placed in context. As Sanofi accurately asserts, "[t]hose references concerned where to put the drug label in order to minimize the risk of medication errors and how to protect the insulin cartridge integrated into the device." Reply at 4-5 (citing SAC Ex. N at 68-78, 98-101). A fair reading of the referenced communications shows that the FDA approved SoloSTAR as a "disposable insulin injection device." SAC Ex. D; Cf. SAC ¶ 204. It is consistently referred to by the FDA as a "device." See SAC Ex. N at 68, 71, 74, 76. The record compels the conclusion, as detailed in this court's earlier Order, that the SoloSTAR was not just packaging but was approved as a drug delivery system. Order at 20-21.

Need to Claim the Drug Product

As before, the plaintiffs next allege that Sanofi was unreasonable in listing the '864 Patent because it does not claim the relevant drug or drug product. They assert that it was improper to list the '864 Patent, which claims only components of an injector pen but does not mention Lantus SoloSTAR, or insulin glargine, because the Regulations provide that "[f]or patents that claim a drug product, the applicant must submit information only on those **patents that claim the drug product**, as defined in § 314.3, that is described in the pending or approved NDA." 21 C.F.R. § 314.53(b)(1) (emphasis added). The plaintiffs argue that since the '864

Patent does not expressly mention Lantus, Lantus SoloSTAR, or insulin glargine, it is improper to list it in the Orange Book as claiming Lantus SoloSTAR. This court does not agree.

As detailed in this court's earlier Order, the FDA's guidance regarding what a patent must expressly claim is ambiguous and is reasonably read to allow for the listing of the '864 Patent. The FDA has expressly interpreted "drug products", for which patents must be listed in the Orange Book, to include "pre-filled drug delivery systems." See FDA Response. Similarly, as detailed above, the FDA has recognized that insulin injector pens constitute "pre-filled drug delivery systems" and it approved SoloSTAR as a "disposable insulin injection device." Hence, it is reasonable to interpret the FDA Regulations as requiring the listing of patents for devices such as SoloSTAR regardless of whether the patent itself expressly references insulin glargine, or insulin glargine in conjunction with the pen-type injector. See SAC ¶ 272.

This court previously held on this point that "even assuming such a 'claim' must be made in the patent, it is not clear whether or not the 'claims' of the '864 patent, which are for a drug delivery device which includes a dose dial sleeve and a dose limiting mechanism, among other things, are sufficient to satisfy any such requirement." Order at 21. The court hereby affirms its prior ruling. The '864 Patent indisputably claims components of the Lantus SoloSTAR, which, as addressed *supra*, Sanofi correctly had reason to believe met the definition of "drug product" under the ambiguous FDA guidance. The plaintiffs have not alleged facts which show that it was unreasonable for Sanofi to list patents claiming components of that drug product.

The plaintiffs rely on Pfizer, Inc. v. FDA, 753 F. Supp. 171 (D. Md. 1990), to argue that patents for components of a drug product should not be listed. Opp. at 17-18. The court in

Pfizer, however, did not hold that component parts of drugs cannot be listed — rather, the court ruled that listed components must be part of the specific drug "for which the applicant submitted the application." 753 F. Supp. at 176-77.

The listed drug at issue in Pfizer was a "nifedipine solution in a soft gelatin capsule, which Pfizer markets in the United States under the trade name Procardia." Id. at 173. The FDA in that case refused to list Pfizer's '986 patent, "which claimed a tablet formulation of nifedipine[,]" in the Orange Book for Procardia. Id. at 174. The FDA had two principal issues with listing the '986 patent. First, the FDA needed proof that the composition underlying the tablet formulation in the '986 patent was approved. Id. Second, the FDA relied on its own interpretation of the term "drug" to conclude that patents need only be filed when they claim the listed drug or drug product for which the NDA was submitted. Id. at 174-75. While both Procardia, a soft gelatin capsule, and Pfizer's tablet formulation include nifedipine, they were two distinct products. See id. at 176. The court in Pfizer held that a listed patent must claim the approved drug product for which the NDA was submitted – in that case Procardia. Id. Pfizer could not submit a patent for a different product just because it shared an active ingredient with Procardia. Pfizer was not submitting components of Procardia itself, but a patent for a different product which shared a component with Procardia.[2] In the instant case, by comparison, Sanofi's patent listed a component of Lantus SoloSTAR, the relevant approved drug product. Including the '864 Patent in the Orange Book is entirely consistent with Pfizer.

[2] The Pfizer court's discussion of the definition of "drug" recognized that it includes component parts of the final drug. Id. at 176 (citing 21 U.S.C. § 321(g)(1)); see also United States v. Generix Drug Corp., 460 U.S. 453, 459, 103 S. Ct. 1298, 1301-02, 75 L. Ed. 2d 198 (1983) ("The term 'drug' is plainly intended throughout the Act to include entire drug products, complete with active and inactive ingredients."). Recognizing component parts of a drug product is entirely consistent.

Finally, the plaintiffs disagree with this court's interpretation of correspondence between companies and the FDA, which evidence confusion in the industry over the very question presented by this litigation. See, e.g., Letter from GSK to FDA, Docket No. FDA-2005-A-0476 (Feb. 11, 2009), available at https://www.regulations.gov/document?D=FDA-2005-A-0476-0004 ("in the absence of further guidance from the FDA, [GSK] has modified its Orange Book listing practice to list those patents . . . that claim all or a portion of integrated drug-device products, regardless of whether the approved drug substance is specifically mentioned in the claims of such patents."). This court also took judicial notice of responses from the FDA, including a 2011 response to an inquiry from Forest Laboratories, Inc., in which the FDA wrote that "due to the need to address other Agency priorities," it "has been unable to reach a decision" on "whether a patent that claims a drug delivery device whose use is integral to the administration of the active ingredient and the approval of the NDA, but that does not claim the active ingredient of the approved drug product, should be submitted for listing in [the Orange Book]." Interim Response to Forest Laboratories, Inc., Docket No. FDA-2011-A-0363 (Nov. 7, 2011), available at https://www.regulations.gov/document?D=FDA-2011-A-0363-0008.

The plaintiffs claim that the letters show, not confusion, but rather an admission by industry members that the current framework does not allow for the listing of patents unless that patent explicitly claims the active drug substance. The court takes judicial notice of the letters themselves, and is not bound to accept the interpretation of their content provided by either party. See OrbusNeich Med. Co. v. Boston Sci. Corp., 694 F. Supp. 2d 106, 111 (D. Mass. 2010) ("The public filing of [a] document with a regulatory agency [] makes it a proper subject of judicial notice, at least with regard to the fact that it contains certain information, though not

as to the truth of its contents."). The letters, posing the question of whether component patents must be listed, further show what this court has held – that the ambiguous listing requirements in this area allow for Sanofi's interpretation permitting the listing of the '864 Patent.

For the foregoing reasons, the plaintiffs again fail to state a claim for Sherman Act violations based on the Orange Book listing of the '864 Patent.

B. Litigation Against Lilly

The plaintiffs also ask this court to reconsider its prior order dismissing their sham litigation claim. They contend that Sanofi engaged in exclusionary conduct through "[c]ommencing and maintaining a sham litigation against Lilly to delay introduction of competing insulin glargine products into the U.S. market." SAC ¶ 498. The plaintiffs further claim that "Sanofi's suit against Lilly was objectively baseless and motivated by a subjective desire to delay competition in the insulin glargine market." Id. ¶ 499. This court previously dismissed the plaintiffs' sham litigation claim regarding the Lilly lawsuit. The allegations in the Second Amended Complaint do not compel a different result.

Once Lilly filed its paragraph IV certification, Sanofi had the statutory right to sue under 35 U.S.C. § 271(e)(2)(A). A paragraph IV certification is deemed to be "a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). Importantly, while a patent holder has the right to sue upon receipt of a paragraph IV certification, it is not obligated to do so.

The filing of a lawsuit is generally protected activity under the First Amendment, as recognized by the Noerr-Pennington doctrine. E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961); and United Mine Workers of Am. v. Pennington, 381 U.S. 657, 85 S. Ct. 1585, 14 L. Ed. 2d 626 (1965). However, this immunity is lost if the lawsuit is a "sham." See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-02503, 2015 WL 5458570, at *11 ("Under the Noerr-Pennington doctrine, filing a lawsuit is protected under the First Amendment unless the lawsuit is a 'sham.'" (citing Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61, 113 S. Ct. 1920, 1928, 123 L. Ed. 2d 611 (1993))).

The Supreme Court has identified a two-part definition for sham litigation.

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor ....

Prof'l Real Estate Investors, Inc., 508 U.S. at 60-61, 113 S. Ct. at 1928 (internal quotations, citations, and emphasis omitted). To prevail, "a plaintiff must allege that both prongs of the test are met." United Food & Commercial Workers v. Novartis Pharm. Corp., 902 F.3d 1, 13 (1st Cir. 2018). In the instant case, Sanofi contends that the plaintiffs have failed to allege that its litigation to enforce the '864 Patent was "objectively baseless." See, e.g., id.; see also 800 Adept, Inc. v. Murex Sec., Ltd., 539 F.3d 1354, 1370 (Fed. Cir. 2008) (to prove objectively baseless prong, the plaintiff had to prove the defendant "had no reasonable basis to believe

that its patent claims were valid or that they were infringed[.]"). This court agrees, and concludes that the plaintiffs have not alleged sufficient facts to make the necessary showing.

Plaintiffs argue that they have cured deficiencies from their previous complaint related to the Lilly sham litigation claim. Opp. at 28-31. The court disagrees. This court found the following in its prior Order:

> According to the Amended Complaint, prior to bringing suit Sanofi had the pages of Lilly's § 505(b)(2) application that (1) showed the list of ingredients of Lilly's NDA product, and (2) identified the type of injector pen by which the Lilly NDA product would be administered. Other than repeatedly stating that the documents showed that Lilly's products would not infringe any of the claims in the two injector pen patents (the '864 and '044 patents) or any claims in the two vial formulation patents (the '652 and '930 patents), the plaintiffs have offered no facts in support of these conclusions. Since this court must disregard conclusory allegations of fact and law, the allegations of the Amended Complaint are insufficient to show that the underlying lawsuit lacked any reasonable merit.

Order at 27 (internal citations and quotations omitted). This court also found that other factors supported the conclusion that the underlying lawsuit was not objectively baseless, including the fact that Sanofi was enforcing valid patents in the face of a paragraph IV certification, that the litigation was hard fought on issues related to the '864 Patent, and that the settlement included favorable terms to Sanofi.

The plaintiffs have amended their Complaint to include facts they believe are sufficient to show that Sanofi's lawsuit against Lilly lacked any reasonable merit. First, the plaintiffs allege in detail the differences between the two pens. SAC ¶¶ 333-343. They assert that, based on those differences, "[n]o reasonable pharmaceutical company in Sanofi's position would realistically expect to succeed in proving infringement." Id. ¶ 332. Next, the plaintiffs assert that if there was a valid basis for infringement, Sanofi would have sued Lilly earlier, when Lilly

used its KwikPen in connection with another insulin product Humalog. Id. ¶¶ 289-298. The plaintiffs contend that since "Sanofi never took the position that Lilly's KwikPen infringed Sanofi's initial injector pen patents, let alone sue Lilly for infringement[,]" Sanofi had no reasonable basis to claim that the KwikPen infringed Sanofi's patents in connection with Lantus or Lantus SoloSTAR. Id. ¶ 298. Finally, the plaintiffs allege that when Sanofi launched a follow-on version of Lilly's Humalog product using its SoloSTAR pen, Sanofi filed a paragraph IV certification alleging that "Lilly's '132 patent was 'invalid, unenforceable, or will not be infringed' by Sanofi's Admelog SoloSTAR product." Id. ¶ 438. The plaintiffs allege that Sanofi's paragraph IV certification in that instance contradicts its position in the Lilly litigation that Basaglar infringed the '864 Patent. See id.

Even considering these new allegations, however, the plaintiffs have failed to allege sufficient facts to establish that Sanofi's suit against Lilly ("Sanofi I") was objectively baseless. "A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent . . . is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment." United Food & Commercial Workers Unions v. Novartis Pharm. Corp., No. 15-12732, 2017 WL 2837002, at *11 (D. Mass. June 30, 2017) (internal quotation and citation omitted), aff'd, 902 F.3d 1 (1st Cir. 2018). It does not matter whether Sanofi would have prevailed at trial. If Sanofi had even a colorable claim of infringement, it is afforded Noerr-Pennington immunity. Id.; see also Asahi Glass Co. v. Pentech

Pharm., Inc., 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003) ("to avoid turning every patent case into an antitrust case, some threshold of plausibility must be crossed at the outset before a patent antitrust case should be permitted to go into its inevitably costly and protracted discovery phase . . . the determination of whether such a suit is a sham depends not on what the patentee believes but on the nature of and the underlying merits of the patentee's case." (internal citations and quotations omitted)). Thus, even if the plaintiffs are right that Lilly would have ultimately prevailed at trial, that is not the question before the court. The sham litigation exception to the Noerr-Pennington doctrine was not intended to provide all third parties with an opportunity to re-litigate cases. The doctrine was reserved for those cases in which the record shows that the suit was objectively baseless.

None of the plaintiffs' new allegations show that Sanofi's suit was objectively baseless. While the plaintiffs now provide the court with ample allegations showing the differences between the injector pens, these differences do not objectively show that Lilly's product did not infringe Sanofi's '864 Patent. Despite the alleged differences between the pens, the underlying litigation docket shows a hard fought case in which non-infringement was anything but clear.[3] See AstraZeneca AB v. Mylan Labs., Inc., Nos. 00-6749, 03-6057, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) (finding that the underlying lawsuit was "hard-fought and close" and that such an "outcome hardly bespeaks baseless litigation."). For example, the record in Sanofi I is clear that Sanofi was asserting that Lilly's pen violated the claims in the '864 Patent. See Sanofi I Joint Claim Construction Brief (Docket No. 149) at 1. Sanofi's contention that the

[3] The court takes judicial notice of the underlying litigation. Maher v. Hyde, 272 F.3d 83, 86 n.3 (1st Cir. 2001) (holding that a court may take judicial notice of the docket of any court case).

'864 Patent had been infringed formed the basis of many of Sanofi's discovery requests. See, e.g., Sanofi I Docket No. 224 at 1 ("Lilly's accused product includes a pen containing various components that, when assembled, combine to form a closing mechanism. Sanofi's asserted device patents include claims to injection devices having particular components, and Sanofi must therefore be able to analyze the structure of the internal components of Lilly's accused device."); see also Docket Nos. 215, 227 (discovery letters).

The court in Sanofi I conducted an extensive claims construction process in which the court accepted some of each party's constructions of the '864 Patent. Sanofi I Docket No. 192. The extent of the litigation negates the plaintiffs' assertion that no reasonable pharmaceutical company would expect to succeed on infringement claims. The fact that the pens had many differences does not show otherwise.

The plaintiffs' allegations regarding Sanofi's conduct related to another insulin product Humalog are also unsuccessful in showing that the underlying suit was baseless. Sanofi's decision not to sue Lilly previously, and decision to file a paragraph IV certification with regard to another drug product, do not show that Sanofi's belief in this particular instance was baseless. Those allegations, even if true, do not show that Sanofi had no reasonable expectation of winning its suit against Lilly concerning this product, Basaglar.[4]

Finally, the settlement between Sanofi and Lilly in the underlying lawsuit provides further support for the conclusion that the lawsuit was not baseless. See Toyo Tire & Rubber

[4] This conclusion is supported by the fact that these facts were all known at the time of Sanofi I and Lilly raised some of the same arguments yet nevertheless proceeded towards trial and eventual settlement in Sanofi I. See Sanofi I Docket No. 149 at 3 ("the injector pen part patents were never asserted against Lilly's marketed KwikPen product.").

Co., Ltd. v. Atturo Tire Corp., No. 14-0206, 2017 WL 1178224, at *4 (N.D. Ill. Mar. 30, 2017) ("courts have invariably held that lawsuits terminating in favorable settlement are also objectively reasonable and are not shams"). Under the terms of the settlement, Lilly was granted a royalty-bearing license such that Lilly could manufacture and sell Basaglar in the KwikPen device globally. SAC ¶ 375. Sanofi, for its part, gained royalties and a delay in Lilly coming to market. Lilly gained the ability to come to market before the expiration of the patents at issue, including the '864 Patent. See id. The court is certainly aware that "[p]arties may settle a litigation for a variety of reasons independent of the merits of the claims." Morton Grove Pharm. Inc. v. Par Pharm. Co., No. 04-7007, 2006 WL 850873, at *11 (N.D. Ill. Mar. 28, 2006) (internal citations omitted). This court acknowledges both parties' arguments related to the import of the settlement, and simply notes that the existence of such a settlement supports the conclusion that Sanofi's underlying infringement claim was at least colorable. For the foregoing reasons, the plaintiffs have failed to state a claim for antitrust violations related to sham litigation.

C. Serial Petitioning

The court must next address the plaintiffs' added allegations related to serial petitioning. The plaintiffs argue that Sanofi has filed two additional lawsuits against Merck and Mylan, which, when assessed in connection with the Lilly lawsuit, constitute a "pattern of anticompetitive petitioning for which [Sanofi] is independently liable under federal antitrust law, even if each act of petitioning is not independently objectively baseless."[5] SAC ¶ 500. The plaintiffs

[5] The lawsuit with Merck is Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp., No. 16-00812 (D. Del. filed Sept. 16, 2016). The parties completed a five day bench trial on June 4, 2018 and have

allege that "[s]imply by filing those suits (which were just as meritless as Sanofi's suit against Lilly), Sanofi triggered regulatory stays that [are] delaying full competition in the Lantus and insulin glargine market lasting at least into 2020." Id. ¶ 11. The plaintiffs claim this is particularly harmful to purchasers because, even though Lilly's product is now on the market, "the largest drop in product price occurs when the number of follow-on products in the market goes from one to two[.]" Id. ¶ 424.

As relevant to the Merck lawsuit, Merck submitted an application for its version of insulin glargine on May 31, 2016. Id. ¶ 405. Merck "included a paragraph IV certification to the laundry list of patents then listed in the Orange Book as covering Lantus and Lantus SoloSTAR, on August 4, 2016." Id. ¶ 407. The plaintiffs allege that Sanofi "refused to accept or review portions of Merck's NDA to determine if it had a viable, non-frivolous claim of patent infringement." Id. ¶ 410. "Instead, on September 16, 2016, Sanofi sued Merck on [] ten patents in the United States District Court for the District of Delaware." Id. ¶ 411.

The second lawsuit the plaintiffs rely on is against Mylan. The plaintiffs allege that "rather than wait for Sanofi to sue Mylan and block competition, Mylan brought the fight to Sanofi[.]" Id. ¶ 426. "On June 5, 2017, Mylan filed with the Patent Trials and Appeals Board ("PTAB") petitions for inter partes review [ ] of Sanofi's vial formulation patents – the '652 patent and the '930 patent." Id. ¶ 427. The plaintiffs assert that "Sanofi opposed the petitions, but on December 13, 2017, the PTAB granted Mylan's petitions – meaning Mylan had demonstrated a 'reasonable likelihood of success' in showing at least one claim of each patent

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submitted post trial briefing. The lawsuit with Mylan is Sanofi-Aventis U.S. LLC v. Mylan N.V., No. 17-09105 (D.N.J. filed Oct. 24, 2017). The litigation is ongoing.

would be found invalid – and instituted an inter partes review of the vial formulation patents." Id. ¶ 428 (internal punctuation omitted). Mylan separately filed an application "seeking permission to manufacture, market, and sell a follow-on version of Lantus SoloSTAR. Contained within its application was a paragraph IV certification that the plethora of vial formulation patents and injector pen patents listed under Lantus in the Orange Book were invalid, unenforceable, or would not be infringed by Mylan's proposed follow-on insulin glargine product." Id. ¶ 430. As with Merck, the plaintiffs claim that Sanofi "refused to accept or review portions of Mylan's NDA to determine whether it had any viable, non-frivolous claim of infringement against Mylan." Id. ¶ 433. "Sanofi sued Mylan on October 24, 2017, alleging that Mylan infringed every one of Sanofi's eighteen injector pen patents and vial formulation patents." Id. ¶ 434. As a result of the lawsuit, "the FDA was automatically prohibited from approving Mylan's product for 30 months, or until March 18, 2020." Id. ¶ 435.

The plaintiffs allege that these two lawsuits, which were filed in response to paragraph IV certifications, subject Sanofi to antitrust liability regardless of their merit. The court does not agree. In its recent decision affirming summary judgment for a competitor in the face of allegations of serial petitioning, the First Circuit noted that although not every suit need be baseless in order for a serial petitioning claim to survive, "the task here is to identify sham litigation, not probable winners. And while we can see the logic inherent in reasoning that a nonfrivolous suit might be viewed differently when flown in a flock of frivolous suits, we see little logic in concluding that an exercise of the right to file an objectively reasonable petition loses its protection merely because it is accompanied by other exercises of that right." P.R. Tel. Co. v. San Juan Cable LLC, 874 F.3d 767, 772 (1st Cir. 2017). In concurring, Judge Barron, joined by Judge

Torruella, explained that in evaluating serial petitioning cases, the court relies "on a more record-based, case-specific line of reasoning that . . . leaves open the possibility that . . . a monopolist might be liable under the antitrust laws for engaging in a pattern of petitioning, even though no single filing in that pattern is objectively baseless." Id. at 773. Judge Barron explained further that "[t]he antitrust violation – if it exists – in a pattern case of that kind inheres in the monopolist's use of the petitioning process to make the costs of the rival's petitioning activity so high that the rival cannot secure the legal relief that would enable it actually to become a competitor." Id. at 776. Judge Barron noted that "no circuit has actually permitted a suit to go forward in which the underlying petitions were not baseless and there was no clear and convincing evidence that an alleged monopolist sought to use the govern-mental process [] as an anticompetitive weapon." Id. at 777 (citations, quotations, and emphasis omitted). The court does not find, in the allegations of the Second Amended Complaint, facts related to these three lawsuits to meet the high bar necessary for the plaintiffs to make a plausible serial petitioning claim. Each suit followed a paragraph IV certification, an act of infringement that permits a company to sue on a colorable claim. Sanofi contends that it did not fully review the records before engaging in litigation in part because Merck and Mylan demanded burdensome confidentiality agreements. Reply at 14. Even if Sanofi did not fully review Merck and Mylan's applications, and even if the PTAB made a preliminary ruling in Mylan's favor, Sanofi has a protective right to sue and defend colorable claims related to its listed patents. The plaintiffs have neither pleaded a plausible case that these suits were individually baseless, nor have they pleaded a plausible case that Sanofi, through filing these

lawsuits, used the governmental process as an anticompetitive weapon. The plaintiffs' antitrust claims, as premised on serial petitioning allegations, fail to state a claim.

D. Causation

The court is cognizant of the fact that the '864 Patent is not the only Orange Book listing and litigated patent the plaintiffs complain of. In fact, the Second Amended Complaint adds even more Orange Book listing claims, asserting that "[e]ven after Sanofi's litigation with Lilly, it expected other companies would soon seek to create affordable follow-on insulin glargine products. To further frustrate those efforts, Sanofi obtained and then listed in the Orange Book an additional *thirteen* patents over its SoloSTAR injector pen." SAC ¶ 389 (emphasis in original). These Sherman Act claims, as based on these other patents, fail for lack of causation.

"An antitrust plaintiff must prove a causal connection between the antitrust violation and actual damages suffered." In re Wellbutrin XL Antitrust Litig., Nos. 08-2431, 08-2433, 2012 WL 1657734, at *33 (E.D.P.A. May 11, 2012). In an antitrust class action, "individual injury (also known as antitrust impact) is an element of the cause of action; to prevail on the merits, every class member must prove at least some antitrust impact resulting from the alleged violation." In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008). The plaintiffs have alleged harm from Sanofi's practices "between February 13, 2015 and December 31, 2016 or until the anticompetitive effects of Sanofi's conduct cease[.]" SAC ¶ 486. As addressed above, the plaintiffs have failed to state a plausible claim for relief based on the listing of the '864 Patent or the litigation enforcing that patent against Lilly, which ended in a settlement agreement that delayed Lilly's market entry until December 2016.

The plaintiffs argue that even if Sanofi's conduct related to the '864 Patent were valid, the thirty-month stay provided for by statute expired on June 20, 2016, six months prior to Lilly's product coming to market. Opp. at 34-35. The plaintiffs seem to be arguing that there were damages during that additional period for which the '864 Patent was not an independent bar. That delay, however, was the product of a settlement agreement entered into between the parties in Sanofi I on September 28, 2015, well before the expiration of the stay. SAC ¶ 375. As explained above, when a party sues on a paragraph IV certification, as Sanofi did here, "the FDA will not grant final approval to the [new drug application] until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the [new] product." 21 U.S.C. § 355(c)(3)(C). Where, as here, the court endorsed a settlement prior to the expiration of 30 months, Sanofi is entitled to any additional delay embodied in that settlement.

Thus, the '864 Patent, and the settlement based thereon, stood as a lawful bar to Lilly's market entry, and the plaintiffs cannot show that Sanofi's conduct related to any other patent caused harm from Lilly's delay during that time period. Additionally, in light of this court's dismissal of the plaintiffs' serial petitioning claim alleging harm from the Merck and Mylan suits, the plaintiffs have failed to show that Sanofi can be held liable for actions causing market delay after December 31, 2016.

E. Claim of Overall Scheme

Finally, the court addresses the fact that the plaintiffs have not simply alleged that the Orange Book listings and the litigations against Lilly, Merck, and Mylan violated the antitrust laws, but that these actions collectively create an "illegal scheme to prevent, delay, and/or

minimize the success of the introduction into the United States marketplace of any competing versions of [] insulin glargine products[.]" SAC ¶ 502. A court "can consider the individual aspects of [a scheme] claim so long as it keeps the larger scope of the scheme in context." In re Asacol Antitrust Litig., 233 F. Supp. 3d 247, 261 (D. Mass. 2017). "In antitrust cases in which a scheme is alleged, 'plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.'" Id. (quoting Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 698-99, 82 S. Ct. 1404, 1410, 8 L. Ed. 2d 777 (1962)). However, "if all we are shown is a number of perfectly legal acts, it becomes much more difficult to find overall wrongdoing. Similarly, a finding of some slight wrongdoing in certain areas need not by itself add up to a violation. We are not dealing with a mathematical equation. We are dealing with what has been called the 'synergistic effect' of the mixture of the elements." City of Anaheim v. S. Cal. Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992) (quoting City of Groton v. Conn. Light & Power Co., 662 F.2d 921, 929 (2d Cir. 1981).

A consideration of the overall mixture of alleged conduct in this case does not warrant a different conclusion than does the evaluation of each element. As shown above, the plaintiffs have not plausibly shown that Sanofi engaged in the improper practice of Orange Book listing and suing competitors to cause anticompetitive injury. The plaintiffs' antitrust claims, as premised on an overall scheme of improper listings and improper litigations, are dismissed.

F. Market Power

As the court concludes that the Second Amended Complaint fails to adequately plead an improper means of acquiring monopoly power, this court need not address the parties'

arguments over whether the plaintiffs have adequately pled that Sanofi possessed monopoly power in the relevant market.

V. CONCLUSION

For the reasons herein, the plaintiffs have failed to state a claim on which relief can be granted for monopolization or attempted monopolization. The Motion to Dismiss (Docket No. 54) is hereby ALLOWED and the Second Amended Complaint is dismissed with prejudice.

/ s / Judith Gail Dein
Judith Gail Dein
United States Magistrate Judge